

Appin No. 10/826,420
Reply to Office Action of October 12, 2006

AMENDMENTS TO THE DRAWINGS:

Please amend Fig. 2 by replacing the lower reference number 2 with reference number 4, as shown in the attached Annotated Sheet.

Please amend Fig. 4 by replacing reference number 4 with reference number 2, as shown in the attached Annotated Sheet.

REMARKS

In the Office Action of October 12, 2006, the specification was objected to for failing to provide proper antecedent basis for subject matter claimed in claims 11-13. The specification was also objected to for failing to properly indicate trademark status at certain points. In response, the specification has been amended at paragraph [00026] to provide antecedent basis for the subject matter of claims 11 and 12 (i.e., sequential or simultaneous processing of blood in the initial collection chamber). The specification has also been amended at paragraph [00027] to provide antecedent basis for the subject matter of claim 13 (i.e., pooling together blood from other blood sources and flowing the pooled blood into the flow path for processing through the fluid circuit). As this subject matter was included in the claims as filed, it is respectfully submitted that these changes do not constitute new matter. Additionally, paragraphs [0004] and [00018] have been amended to indicate trademark status of certain terms. Finally, the specification has also been amended at various locations to correct typographical errors.

In the Office Action of October 12, 2006, the abstract was objected to for using legal phraseology. Applicants are unsure of what the Examiner considers to be "legal phraseology," but the abstract has been amended at various locations to remove phrases and terms which may be the source of the Examiner's concern. If the abstract remains objectionable, applicants respectfully request a more specific objection to facilitate a proper response.

By this response, applicants also voluntarily amend Figs. 2 and 4, which incorrectly identify the fluid circuit and separation controller, respectively. As required, annotated and replacement sheets are submitted herewith. These amendments bring the figures into conformity with the description, so they do not constitute new matter and it is respectfully requested that they be entered.

Turning now to the claims, all of original claims 1-18 stand rejected. Claims 8 and 9 have been rejected for using the term "the reusable device" without providing proper antecedent basis. These claims have been amended to instead refer to "the reusable controller," which finds antecedent basis in claim 1. Claims 1-3, 7, 10-13, and 15-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,653,887 ("Wahl"); claims 8 and 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wahl; and claims 4-6 and 14 stand rejected as being unpatentable over Wahl in view of U.S. Patent No. 6,695,803 ("Robinson").

It is respectfully submitted that amended claim 1 is neither anticipated nor made obvious by the prior art of record. Amended claim 1 requires, among other things, the step of "disconnecting the source from the fluid circuit before all of the blood in the fluid circuit is processed in the processing chamber." Wahl involves a typical apheresis method, wherein the source is not disconnected from the fluid circuit until the end of the procedure. In particular, the apheresis method described in Wahl includes loading and preparing a blood separation device (column 51, lines 31-64), connecting a donor to a fluid circuit (column 51, line 65 – column 52, line 11), collecting and processing all of the blood collected from the donor (column 52, lines 12-23), and then a final step of

unloading the fluid circuit from the separation device -- after all of the blood from the donor has been processed (column 52, lines 24-35). As clearly described from column 53, line 61 – column 61, line 45, part of the final step also includes disconnecting the donor from the fluid circuit and disposing of the fluid circuit (column 61, lines 27-45). Hence, Wahl fails to teach or suggest the method of amended claim 1, for the reason that it does not describe a method of processing blood after the source is disconnected from the fluid circuit.

In the present Office Action, the Examiner points to two passages of Wahl (column 55, lines 60-67 and column 59, lines 1-5) for the proposition that Wahl teaches disconnecting a blood source from a fluid circuit. However, these passages fail to describe the claimed method as amended. First, lines 60-67 of column 55 refer to clamping the donor access line to perform a pre-donation pressure test on the fluid circuit. This step is a part of the initial loading procedure which takes place before the donor is even connected to the fluid circuit and before blood flow has begun. Thus, this passage also fails to teach or suggest the method of amended claim 1.

Second, lines 1-5 of column 59 refer to closing or sealing fluid communication from the donor to a sample subassembly 46, which is only a portion of the entire fluid circuit 10. This sealing/sampling step is relatively brief and performed before beginning any blood processing, such that the donor remains fluidly connected to the remainder of the fluid circuit during this step for subsequent collection and processing. As further indication that the donor remains connected, Wahl describes, at lines 27-45 of column 59, that the system provides a time display shown after the sampling/sealing step,

which shows time remaining in the collection procedure. Further, Wahl teaches a rinseback step of selected blood components to the donor prior to the final disconnection and unloading step (see lines 8-11 of column 61), so there is no motivation to prematurely disconnect the donor from the fluid circuit, and doing so would fundamentally alter the system's operation. Hence, it is clear that the donor remains connected to the fluid circuit throughout this sampling step for subsequent blood processing, in contrast to the method of claim 1 as amended. For at least these reasons, it is respectfully submitted that claim 1 and all claims depending therefrom are in condition for allowance.

Independent claim 15 has also been rejected for being anticipated by Wahl, but it is respectfully submitted that it is allowable for similar reasons as amended claim 1. In particular, claim 15 as amended requires, *inter alia*, "a fluid circuit assembly . . . adapted for processing blood while in fluid communication with a blood source and after fluid flow through [a] source flow path is discontinued." As described in greater detail above, Wahl does not teach a fluid circuit that allows for "post-disconnection" or "post-donation" processing, so claim 15 and all claims depending therefrom are believed to be in condition for allowance.

Finally, new claims 19-21 have been added. Claim 19 is directed to a feature of original independent claim 15, so it does not constitute new matter. As for new claims 20 and 21, these claims are fully supported by the specification, for example at paragraph [00020], which describes alternative arrangements whereby the fluid circuit may be provided with or without an initial collection chamber as such (i.e., with or

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without a collection chamber that is separate from the processing chamber). It is respectfully submitted that these claims are in condition for allowance for reasons substantially identical to those described herein with reference to amended claim 1.

CONCLUSION

For the above reasons, it is respectfully submitted that all of the claims are in condition for allowance. Accordingly, reconsideration and allowance are respectfully requested. Consideration of the information disclosure statement filed herewith is also respectfully requested. Please charge deposit account 50/1039 for any fees required by this amendment and/or the information disclosure statement.

Respectfully submitted,

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FIG.2

